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# NOTICE OF ALLOWANCE AND FEE(S) DUE

20462

7590

04/24/2008

SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939

EXAMINER				
MRUK, BRIAN P				
ART UNIT	PAPER NUMBER			
1796				

DATE MAILED: 04/24/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543.012	07/22/2005	Kamlesh H. Patel	PU60045	3959

TITLE OF INVENTION: SOLID DISPERSION COMPOSITIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	07/24/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where m

appropriate. All further indicated unless correct maintenance fee notifica	correspondence including delay or directed off tions.	ng the Patent, advance onerwise in Block 1, by (	orders and notification of a) specifying a new cor	f maintenance fees respondence address	will be s; and/or	mailed to the current c (b) indicating a separ-	correspondence address as ate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			F	Note: A certificate of mailing can only be used for domestic mailings of th Fee(s) Transmittal. This certificate cannot be used for any other accompanyin papers. Each additional paper, such as an assignment or formal drawing, much ave its own certificate of mailing or transmission.			
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SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539		W2220 IS S au tu	Certificate of Mailing or Transmission  I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.				
KING OF PRUS	SSIA, PA 19406-09:	39	Γ				(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	OR	ATTO:	RNEY DOCKET NO.	CONFIRMATION NO.
10/543,012	07/22/2005	•	Kamlesh H. Patel			PU60045	3959
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nonprovisional	NO	\$1440	\$300	\$0		\$1740	07/24/2008
EXAM	IINER	ART UNIT	CLASS-SUBCLASS	╛			
MRUK, I	BRIAN P	1796	510-441000				
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3. ASSIGNEE NAME A	ND RESIDENCE DATA	A TO BE PRINTED ON	THE PATENT (print or	type)			
PLEASE NOTE: Unirecordation as set fort  (A) NAME OF ASSI	h in 37 CFR 3.11. Comp	ified below, no assignee pletion of this form is NO	data will appear on the T a substitute for filing (B) RESIDENCE: (CI	in assignment.			cument has been filed for
(A) NAME OF ASSI	OIVLAL		(b) RESIDENCE. (CI	IT and STATE OR	COONI	K1)	
Please check the appropr	iate assignee category or	categories (will not be p	rinted on the patent):	🗖 Individual 📮 C	Corporati	on or other private grou	p entity 🗖 Government
4a. The following fee(s)	are submitted:	4	b. Payment of Fee(s): (P		ıny prev	iously paid issue fee sl	nown above)
Issue Fee			A check is enclosed.				
	No small entity discount p # of Copies		☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any				ciency or credit any
Advance Order	# of copies		overpayment, to De	posit Account Numb	per	(enclose an	extra copy of this form).
5. Change in Entity Sta	tus (from status indicated s SMALL ENTITY state		□ h Applicant is no l	ongon alaiming SMA	II DND	ΓΙΤΥ status. See 37 CFI	D 1.27(~)(2)
NOTE: The Issue Fee an	d Publication Fee (if rea	uired) will not be accepte	ed from anyone other tha				assignee or other party in
interest as shown by the	records of the United Sta	ites Patent and Trademark	COffice.		,		
Authorized Signature				Date			
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This collection of inform	nation is required by 37 C	CFR 1.311. The informati	on is required to obtain o	or retain a benefit by	the publ	ic which is to file (and	by the USPTO to process)
an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	tiality is governed by 35 d application form to the ions for reducing this bu. /irginia 22313-1450. DC 113-1450.	U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th D NOT SEND FEES OR	1.14. This collection is depending upon the in the Chief Information Off COMPLETED FORMS	estimated to take 12 lividual case. Any c icer, U.S. Patent and TO THIS ADDRES	minutes omment I Traden S. SENI	s to complete, including s on the amount of tim nark Office, U.S. Depar D TO: Commissioner fo	gathering, preparing, and e you require to complete tment of Commerce, P.O. or Patents, P.O. Box 1450,

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20462 7	590 04/24/2008		EXAMINER		
SMITHKLINE BEECHAM CORPORATION			MRUK, I	BRIAN P	
CORPORATE IN	TELLECTUAL PROPI	ERTY-US, UW2220	ART UNIT	PAPER NUMBER	
P. O. BOX 1539 KING OF PRUSS	IA, PA 19406-0939		1796	0	

# **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 481 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 481 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)	Applicant(s)	
	10/543,012	PATEL ET AL.		
Notice of Allowability	Examiner	Art Unit		
	Brian P. Mruk	1796		
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.31:	S (OR REMAINS) CLOSED in ) or other appropriate communication. This application is su	this application. If not included nication will be mailed in due cour	rse. <b>THIS</b>	
1. 🔀 This communication is responsive to 18 April 2008.				
2. ☑ The allowed claim(s) is/are <u>1-19</u> .				
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority u</li> <li>a)  All b)  Some* c)  None of the:</li> <li>1.  Certified copies of the priority documents hav</li> </ul>		r (f).		
2. Certified copies of the priority documents have	e been received in Applicatior	n No		
3. Copies of the certified copies of the priority do	ocuments have been received	in this national stage application	from the	
International Bureau (PCT Rule 17.2(a)).				
* Certified copies not received:				
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDON'THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	MENT of this application.			
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be subn INFORMAL PATENT APPLICATION (PTO-152) which giv</li> </ol>			CE OF	
5. CORRECTED DRAWINGS ( as "replacement sheets") mu	st be submitted.			
(a) $\square$ including changes required by the Notice of Draftsper	son's Patent Drawing Review	( PTO-948) attached		
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date	<u></u>			
<ul><li>(b) ☐ including changes required by the attached Examiner Paper No./Mail Date</li></ul>	's Amendment / Comment or	in the Office action of		
Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in			k) of	
<ol> <li>DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT</li> </ol>			the	
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5 □ Notice of Inf	ormal Patent Application		
<ol> <li>Notice of Traffperson's Patent Drawing Review (PTO-948)</li> </ol>	<u>=</u>	mmary (PTO-413),		
3. ☑ Information Disclosure Statements (PTO/SB/08),	Paper No./N 7. □ Examiner's A	Mail Date Amendment/Comment		
Paper No./Mail Date 3/31/08	<u>_</u>			
4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. ⊠ Examiner's 8	Statement of Reasons for Allowan	.ce	
	/Brian P Mruk/ Primary Examiner, /	Art Unit 1796		

### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance:

Patel et al, U.S. Patent No. 6,248,363, discloses a solid pharmaceutical composition comprising a solid carrier, an encapsulation coating that contains a hydrophilic surfactant, an active ingredient, and a lipophilic surfactant (see abstract and col. 2, lines 58-67). However, patentee differs from applicant in that Patel et al does not teach or suggest in general a water-dispersible particulate composition that contains 0.01-15% by weight of a sparingly water-soluble compound and 85-99.99% of the specific particulatable lipid-based carrier that is required in the instant claims.

Accordingly, the claims viewed as a whole would not have been obvious to one of ordinary skill in the art at the time of the invention after viewing the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian P. Mruk whose telephone number is (571) 272-1321. The examiner can normally be reached on Mon-Thurs (7:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian P Mruk/ Primary Examiner, Art Unit 1796

Brian P Mruk April 20, 2008 Brian P Mruk Primary Examiner Art Unit 1796